

PATENT
Attorney Docket No. LEX-011

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Gillies et al.

CONF. NO.:

8264

SERIAL NO.:

09/780,668

**GROUP NO.:** 

1644

FILING DATE:

February 9, 2001

**EXAMINER:** 

David A. Saunders

TITLE:

ENHANCING THE CIRCULATING HALF-LIFE OF

ANTIBODY-BASED FUSION PROTEINS

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

# THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

#### **REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

(1)	within three (3) months of the <b>filing date</b> of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the <b>date of entry of the national stage</b> as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the <b>first Office action</b> on the merits, or before the mailing of a <b>first Office action</b> after the filing of a request for continued examination under 37 C.F.R. 1.114; or
(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and
	the requisite Statement is below, OR

Third Supplemental Information Disclosure Statement Serial No. 09/780,668 Page 2 of 2 the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or after the mailing date of a final action or notice of allowance but before the payment (3) of the issue fee, AND the requisite Statement is below, AND the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein. It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application. Respectfully submitted, Date: September 28, 2004 Brian Fairchild, Ph.D. Reg. No. 48,645 Attorney for Applicants Testa, Hurwitz, & Thibeault, LLP Tel. No.: (617) 248-7697 High Street Tower 125 High Street Fax No.: (617) 248-7100 Boston, Massachusetts 02110



**FORM PTO - 1449** 

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-011

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/780,668

EXAMINER: David A. Saunders

FILING DATE: February 9, 2001 GROUP: 1644

## **U.S. PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	NA	ME		CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A97	5,601,819	2/11/97	Wo	ng et al.				
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	A99	5,994,104	11/30/99	And	derson et al.				
	A100	6,429,199	8/6/02	Kri	eg et al.	-			
•	A101	6,500,641	12/31/02	2 Che	en et al.			1	
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	A103	6,646,113	11/11/03	B Dre	yfuss et al.				
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	A106	2003/0139365	7/24/03	Lo	et al.				İ
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	A108	2004/0013640	1/22/04	Zar	di et al.		<u> </u>		
	A109	2004/0033210	2/19/04	Gill	Gillies				
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	A111	2004/0053366	3/18/04	Lo	Lo et al.			<del> </del>	
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	A113	2004/0082039	4/29/04	Gill	ies et al.				
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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNT RY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)					
-	C241	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization a Mouse-Human Chimeric Antibody," Cancer Immuno. Immunother., 39:198-204.				
	C242	Conner et al., (2004), "Ex vivo Evaluation of Anti-EpCAM Immunocytokine huKS-IL2 in Ovarian Cancer," <u>J. Immunotherapy</u> , 27:211-219.  de la Salle et al., (1996), "FcyR on Human Dendritic Cells," in <u>Human IgG Receptors</u> , pp. 39-55, van de Winkel et al. (eds.), R.G. Landes Co.				
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	<ul> <li>C247 Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growt Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," J. Immunology, 146(3):1067-1071.</li> <li>C248 Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibod ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u>, 31A(2):261-267.</li> <li>C249 Hank et al., (1996), "Activation of Human Effector Cells by a Tumor Reactive Recombinant Anti-ganglios GD2 Interleukin-2 Fusion Protein (ch14.18-IL2)," <u>Clin Cancer Research</u>, 2(12):1951-1959.</li> </ul>					
	C250	Hurn et al., (1980), "Production of Reagent Antibodies," Methods in Enzymology, 70: 104-142.				
	<ul> <li>C251 Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," J. Immunology, 114(6):1726-1729.</li> <li>C252 Ko et al., (2004), "Safety, Pharmacokinetics, and Biological Pharmacodynamics of the Immunocytokine El 273066 (huKS-IL2)," J. Immunotherapy, 27:232-239.</li> <li>C253 Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in E. Coli. Hum. Antibod. Hybridomas, 3:123-128.</li> </ul>					
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FORM	РТО -	1449	ATTORNEY DOCKET NO.: LEX-011				
		LEMENTAL INFORMATION	APPLICANT(S): Gillies et al.				
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			FILING DATE: February 9, 2001 GROUP: 1644				
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	C254	Maecker et al., (1997), "DNA Vaccination wow." Vaccine, 15(15):1687-1696.	vith Cytokine Fusion Constructs Biases the Immune Reponse to				
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	C257 Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," Cancer Immuno. Immunother., 37:343-349.						
	C258	Pertl et al., (2003), "Immunotherapy with a Posttranscriptionally Modified DNA Vaccine Induces Complete Protection Against Metastatic Neuroblastoma," <u>Blood</u> , 101(2):649-654.					
	C259	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," Prog. Brain Res., 101:201-212					
	C260	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antiob. Hybridomas</u> , 3:19-24.					
	C261	Sallusto et al., (1994), "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor α," J. Exp. Med., 179:1109-1118.					
	C262 Schlom (1991), "Monoclonal Antibodies: They're More and Less Than You Think," in Molecular Foundations of Oncology, pp. 95-133.						
	C263	C263 Weber et al., (2001), "Phase I Trial of huKS-IL2 Immunocytokine in Patients with Prostate Carcinoma: Clinical, PK, and Biological PD Results (Abstract)," American Society of Clinical Oncology Program/Proceedings, 20(Part 1):259a.					
	C264	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," J. Biological Chemistry, 269(36):22839-22846.					
	C265	Gurewich et al., (1988), "Characterization of the Intrinsic Fibrinolytic Properties of Pro-urokinase through a Study of Plasmin-resistant Mutant Forms Produced by Site-specific Mutagenesis of Lysine <sup>158</sup> ," J. Clin. Invest., 82:1956-1962.					
	C266 Miyake et al., (1988), "Synthesis of Recombinant Human Single-Chain Urokinase-Type Plasminogen Activated Variants Resistant to Plasmin and Thrombin," J. Biochem., 104:643-647.						
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FORM	PTO -	1449	ATTORNEY DOCKET NO.: LEX-011			
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	C267	Nelles et al., (1987), "Characterization of Recombinant Human Single Chain Urokinase-type Plasminogen Activator Mutants Produced by Site-specific Mutagenesis of Lysine 158," The Journal of Biological Chemistry, 262(12):5682-5689.				
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